

Remarks

Claims 1-12 are pending. Claims 1, 7 and 9 have been amended in accordance with suggestions by the Examiner to address rejections for lack of antecedent basis. Support for these amendments can be found in the claims and the specification as a whole, and for example, claims 1, 6 and 8.

Applicant has canceled claims 2 and 4 and incorporated the language of claim 4 into amended claim 1, which now recites "and arranged to provide a swirling motion to an ablation fluid flowing into the at least one manifold." Claim 12 has also been amended to depend from claim 1. These amendments find support in the specification as a whole and, for example, paragraph 0069 and original claims 4 and 12.

No new matter is added by these amendments.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claim 1, line 8 to read "the outlet port" to match the same language found earlier in claim 1.

Applicant has also amended claim 7 to indicate that it should depend from claim 6 (not claim 5) in order to provide proper antecedent basis for "the electrode lumen." Similarly, claim 9 has been amended to depend from claim 8 (not claim 7) in order to provide proper antecedent basis for the "the at least one channel" and to match that language found in claim 8.

Each of these amendments have been adopted at the suggestion of the Examiner and, as noted above, find their support in original claims 1, 6 and 8.

Applicant respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102

Rejections under 35 U.S.C. § 102(b) as allegedly being anticipated by Brucker.

Claims 1-4 and 6-9 have been rejected by the Examiner as allegedly being anticipated by Brucker, et al. Office action at 2-3. Regarding claim 1, the Examiner alleges that Brucker discloses an inlet port in communication with a fluid supply, an outlet port in communication with the inlet port and having a larger dimension than the inlet; and a tip member which is an electrode in the ablation fluid path. Office action at page 3.

Applicant respectfully submits that the Examiner has not made out a *prima facie* case for anticipation. As discussed in more detail below, Brucker does not contain all of the limitations found in the claims, nor in the same arrangement as claimed. In particular, neither 1) an outlet port; 2) an inlet which defines a circle; 3) an inlet which inherently provides swirling of the ablation fluid; 4) an electrode housed in an electrode lumen; nor 5) channels in fluid communication with the outlet port as found in Applicant's claims can be found in the cited document.

Without conceding that the Examiner's rejection based on anticipation is proper, in the interest of furthering prosecution, Applicant has amended claim 1 to incorporate the language of canceled claim 4, which states that the at least one inlet port be "arranged to provide a swirling motion to an ablation fluid flowing into the at least one manifold." Support for this amendment is found in the specification as a whole, for example in Paragraph 0069 of the specification, and Applicant's original claim 4.

The Examiner has further alleged that the enlarged opening (58) of Brucker relative to its "inlet" would "inherently provide a swirling of the fluid." Office action at pg. 3. Applicant respectfully asserts that the Examiner has not met the required burden of proof sufficient to support a theory of inherency.

"In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly

inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In the Levy case, the Board reversed on the basis that the Examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency. Furthermore, "[I]nherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)." See also Trintec Industries v. Top-U.S.A. Corp., 295 F.3d 1292, 63 USPQ2d (BNA) 1597 (Fed. Cir. 2002). In this case, there is no discussion of how "swirling" is necessarily present from the content of Brucker.

Applicant has described in paragraph 0069 of the specification how arranging the angle of entry of the at least one inlet port at an angle other than orthogonal to the wall of the circular outlet port would impart a swirl to that flow. One of ordinary skill would instantly recognize that it is Applicant's arrangement of the inlet port with respect to its outlet port which produces the swirling. Applicant respectfully asserts that the Examiner has not provided any reasoning to support how the flow of fluid from the alleged "inlet port" to the alleged "outlet port" of Brucker would inherently impart swirl to the fluid flow. One of ordinary skill would understand that the generation of secondary flows through an enclosed space is highly dependent on geometry and flow path.

The geometry and flow path in Brucker at Fig. 9 shows the fluid first flowing down the "path means" (54) before flowing into element (60) (which the Examiner has alleged is the "inlet port"). The fluid then flows down the straight-pathed "inlet port" into the alleged "outlet port with larger dimension" (58). A closer reading of the Brucker document reveals that the alleged "outlet port" (58) is actually an "annular groove" cut around the entire circumference of the electrode. Brucker at col. 6, line 19. In other words, the view of the alleged "outlet port" presented in Fig. 9 requires close examination. The "outlet port" (58) has walls only on either side (right and left) in this view, it is not contained by any walls forward or back. Thus, the geometry of the "outlet port" in Brucker is very different than the outlet port of Applicant's claims. While Applicant's outlet port shown in the Figures is

similar to a circular vessel (capable of maintaining an induced swirl), Brucker's alleged "outlet port" is really a linear "slot" cut into the electrode. Respectfully, one of ordinary skill would have no reason to suspect that a fluid flowing through a straight channel into what is essentially a straight slot in Brucker would induce any particular secondary flows at all, particularly swirl.

Applicant asserts that Brucker does not contain the element of an inlet port arranged to provide a swirling flow into the manifold and therefore does not contain all of the limitations found in Applicant's amended claim. In addition, the Examiner has not met the required burden for asserting that a swirling flow is inherently produced when a fluid flows through a straight channel into a slot. For at least these reasons, Applicant respectfully requests withdrawal of this rejection.

Rejections under 35 U.S.C. § 102(b) as allegedly being anticipated by Swartz.

Claims 1-9 stand rejected as allegedly being anticipated by Swartz. The Examiner has alleged that Swartz discloses inlet ports, outlet ports, an electrode and a "channel extending into the manifold (304) for delivering fluid through the inlet ports (306)." Office action at pgs. 3-4.

Applicant has amended claim 1 to recite at least one inlet port "arranged to provide a swirling motion to an ablation fluid flowing into the at least one manifold." As argued above with respect to Brucker, Swartz does not contain the element of an inlet port arranged to provide a swirling motion. The alleged "inlet ports" of Swartz cited by the Examiner are far more numerous than the "outlet ports" and are also not physically connected to the "outlet ports". See Swartz at Fig. 10. One of ordinary skill studying Swartz would recognize that by orienting the plurality of openings in all directions surrounding the tube, the intent appears to be to create a uniform distribution of fluid within the lumen of the catheter. There is no indication that swirling is possible or desired. In fact, the configuration of Swartz cited by the Examiner recites that the fluid "pass[es] through the openings . . . in the tubular body and substantially fill[s] the space within the lumen." Swartz at col. 11, lines

23-25. There is absolutely no indication in Swartz that enough pressure is being applied to the fluid to impart any significant secondary flow at all. In fact, the arrangement of Fig. 10 shows larger "outlet parts" at the distal end designed to achieve a uniform flow, which one of skill in the art would assume is to avoid "swirling". Because Swartz does not contain all of the claim limitations of Applicant's amended claim 1, Applicant requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b) as allegedly being anticipated by Tu and also by Bednarek.

The Examiner has further alleged that claim 12 is anticipated by both Tu and by Bednarek. Office action at pg. 4. Without conceding the appropriateness of the Examiner's rejection and in the interest of advancing prosecution, Applicant has amended claim 12 to depend from claim 1. The amendment finds support in the specification as a whole and, for example, in original claim 12.

As argued above with respect to Brucker and Swartz, Applicant respectfully asserts that neither Tu nor Bednarek contain any disclosure of the at least one inlet port arranged to provide a swirling motion into the manifold as found in Applicant's amended claim 1 and upon which claim 12 depends. For at least this reason, the rejection based on anticipation should be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Rejection under 35 U.S.C. § 103(a) as allegedly being unpatentable over Brucker in view of Swartz.

The Examiner has rejected claim 5 as being obvious over the combination of Brucker in view of Swartz. Specifically, the Examiner asserts that one of ordinary skill in the art would combine these documents because one would recognize that various sizes of inlet and outlet ports may advantageously be used. Office action at pg. 5.

In order to make out a *prima facie* case of obviousness, "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998). Additionally, "[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done." In re San Su Lee, 277 F.3d 1338 (Fed. Cir. 2002). "Teachings of references can be combined *only* if there is some suggestion or incentive to do so." ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984). Therefore, the evidence of record must identify an objective source for the motivation to combine Brucker with Swartz in the manner proposed. In re Lee, 277 F.3d at 1343.

Applicant's claim 5 discusses specific size limitations for the inlet and outlet ports in terms of a diameter. The Examiner has alleged that Swartz "specifically indicate[s] size limitations for the inlet and outlet openings that are within the range set forth in applicant's claim 5." Office action at pg. 5. However, as shown above, a closer examination of the Brucker document reveals that the alleged "outlet ports" of Brucker are not circular in the same sense as Swartz. The "outlet ports" of Brucker are actually grooves that encircle the tip of the device. Brucker at Fig. 9 and col. 6, line 19. Thus, in Brucker, the term *diameter* (at least in terms of the "outlet ports") has no meaning. Similarly, the outlet ports of Swartz make no mention or suggestion of grooves.

At best, Brucker and Swartz constitute a confusing combination. The Examiner has not explained how or why one of ordinary skill would abandon the grooves of Brucker to incorporate the specific diameters of Swartz. Because Brucker (with grooves) does not contain "outlet ports" with the same geometry as Swartz (a circle), there would simply be no motivation to consider combining the "diameter" ranges from Swartz with Brucker except through an improper use of hindsight analysis. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985) ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself").

Applicant has amended claim 1, upon which claim 5 depends, to recite at least one inlet port "arranged to provide a swirling motion to an ablation fluid flowing into the at least one manifold." As noted above, neither Brucker or Swartz teach or suggest an inlet port arrangement which would provide swirling. One of ordinary skill would recognize that combining Swartz with Brucker in the manner suggested by the Examiner would not overcome this deficiency.

Applicant respectfully requests withdrawal of this rejection.

Rejections under 35 U.S.C. § 103(a) as allegedly being unpatentable over Swartz in view of Bednarek.

The Examiner has rejected claims 10-12, alleging that Bednarek "teach[es] that it is known to provide the catheter with an arcuate distal shape . . . to facilitate placement at certain cardiac locations" and that providing Swartz with an arcuate distal section is therefore an obvious modification. Office action at pg. 6.

Applicant has amended claim 12 to depend from claim 1. Applicant submits that neither Swartz nor Bednarek teach or suggest an inlet port which provides a swirl to the ablation fluid. Bednarek does not contain or suggest the existence of an inlet port at all and the Examiner has not alleged that it contains one. Furthermore, as argued above, a closer examination of Swartz reveals that secondary flows in the ablation fluid are neither possible or even desired. Indeed, Swartz does not even address this problem.

Applicant respectfully requests withdrawal of this rejection.

Applicant submits that the application is in condition for allowance. Timely notification of allowability is requested.

Applicant requests a three-month extension of time for response to this Office action and has submitted the requisite fee. No additional fees, requests for extension of time, other petitions, additional claim fees, or any other fees are believed to be necessary to

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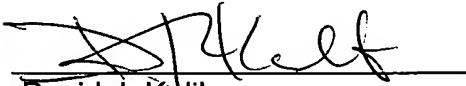
enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, Applicant hereby requests any extensions or petitions necessary and the Commissioner is hereby authorized to charge our Deposit Account No. 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, or if the payment or fee payment information has been misplaced or is somehow insufficient to provide payment, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,

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